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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,135	10/15/2003	Ivan Osorio	539.3167.1	8261

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EXAMINER	
ALTER, ALYSSA MARGO	

ART UNIT	PAPER NUMBER
3762	

NOTIFICATION DATE	DELIVERY MODE
12/22/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ip@fredlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/687,135	OSORIO ET AL.	
	Examiner	Art Unit	
	Alyssa M. Alter	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-16,18-32 and 34-46* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-16,18-32 and 34-46* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *15 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 2, 2011 has been entered.

Response to Arguments

2. Applicant's arguments, see page 11, filed December 2, 2011, with respect to the rejection(s) of claim(s) 1-7, 12-16 and 20-37 under Shaw et al. (US 6,014,587) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Sieracki et al. (US 6,308,102 B1).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claim 1-9, 12-13, 20, 22-29, 34-42 and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by Sieracki et al. (US 6,308,102 B1). Sieracki et al. discloses a patient interactive neurostimulation system that enables patient to operate the medical device in a manual mode. Depicted in figure 14A is a threshold test procedure executed by the patient.

5. Sieracki et al. discloses in col.4, lines 31-42, "it is an essential and novel feature of the present invention that means are provided in the system which pre-sets consistency boundaries for data entered by the patient and which verify that the entered data fall within the consistency boundaries. If the consistency boundaries are exceeded, then the data entered are recycled, and the patient is asked to repeat a response, or the system is checked for hardware failure. This arrangement in the system of the present invention provides for full automation of operation, obtaining of reliable data, and safety for the patient, so that he/she may be confidently left alone to work with the system without intervention by a clinician". Therefore when the first set of information received from a user is determined to exceed the pre-set boundaries, it is considered "not safe" and a corrective action ("recycling" or discarding the data) is executed. If the boundaries are not exceeded then the device continues with the treatment regimen.

6. As to claims 2-3 and 41-42, "if the criteria has been met in decision block 1010, the flow moves to flow block 1030 which is a decision flow block to determine whether the threshold is less than the perceptual. Where the threshold is less than the perceptual, then the process moves to decision flow block 1050. As part of the overall

program, the patient is generally given two tries and if the patient cannot correct the problem on the second try, the flow moves to block 1060 where the threshold procedure is aborted and passes to a re-input of the perceptual"(col. 28, lines 13-22). Therefore, if the system determines that the treatment is not safe (see figure 14A) then the therapy is aborted or terminated and thus re-delivery is prevented (see block 1060 in figure 14A).

7. As to claims 4 and 26, as stated above, by comparing the perceptual threshold and tolerable threshold (cols. 27-28, lines 65-67 and 1-3, respectively) if the therapy is not tolerable then a corrective action is executed. In figure 13D, the discomfort threshold is analyzed. When discomfort is established the corresponding action of determining motor threshold (see block 800) is executed.

8. As to claim 5, based on the information determined during the first threshold determination (first set of information), a second action is executed (drawing 1070 in figure 14A).

9. As to claims 6, the examiner considers the interaction with the drawing, indicating the areas where sensation or stimulation occurred, to be the "labeling with the first set of information" since the drawing is labeled with a response to stimulation.

10. As to claim 7, since the drawings are used to analyze the patient's pain perception, the drawings and labels are necessarily used in subsequent treatments.

11. As to claims 8 and 28, once the first stimulation is applied and the drawings are received the stimulation is again applied (see figure 14B) and a new label of drawing is created (see block 1240) for comparison with the previous.

12. As to claims 9 and 29, since a drawing or label is generated after each threshold determination, the therapy treatments are all considered unique and receive different labels or drawings.

13. As to claim 20, "wherein the nervous system disorder is selected from the group consisting of a disorder of a central nervous system, a disorder of a peripheral nervous system, a mental health disorder, and psychiatric disorder". A nervous system disorder necessarily impacts either the central or peripheral nervous system. Therefore, the system of Sieracki et al. necessarily treats either central or peripheral nervous system disorders.

14. As to claim 22, Sieracki et al. discloses application of electrical stimulation.

15. As to claim 23, "the first treatment therapy is provided to a location of a body selected from the group consisting of a brain, a vagal nerve, a spinal cord, and a peripheral nerve". Treatment that affects the nervous system would *necessarily* affect the brain, spinal cord, vagal nerve *or* peripheral nerve since there isn't a nerve that would not fall into one of these categories.

16. As to claim 24, "the medical device system is selected from the group consisting of an external system, an implanted system, and a hybrid system". The system would necessarily meet this limitation, since the system is either totally implanted, totally external or a combination therefore. There is no additional implantation possibility for medical devices. Therefore, the system of Sieracki et al. meets this limitation.

17. As to claims 34-37, since the system employs a computer, the system necessarily includes "a computer-readable medium" executes "instructions for performing the method recited".

18. As to claim 38, since the system incorporates an interactive external computer, the examiner considers the system to be an external system.

19. As to claim 39, additionally since the system interacts with an implantable device, the system is additionally considered to be an implanted system.

20. As to claim 45, when the proper procedure is not executed the system administers a warning (see examples 1-24, cols. 19-24).

21. As to claim 46, the examiner considers the "perceptual threshold procedure" to be "an indication of degree of tolerance".

Claim Rejections - 35 USC § 103

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

23. Claims 10-11, 14-16, 18-19, 21, 30-32 and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sieracki et al. (US 6,308,102 B1). Sieracki et al. discloses the device substantially as claimed but does not explicitly disclose outputting a notification to a user and rejecting the therapy treatment is not essentially unique. It would have been obvious to one having ordinary skill in the art at the time the invention

was made to modify the treatment therapy to not commence treatment and notify the user when the treatment was not essentially unique in order to provide the predictable results of ensuring that a variety of threshold parameters are observed and not repeated unnecessarily.

24. As to claim 14, 32 and 44, Sieracki et al. discloses the device substantially as claimed but does not explicitly disclose determining the charge density and comparing it to a threshold value. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the comparison of charge density to a threshold value in order to provide the predictable results of ensuring that the patient administer excessive amounts of stimulation to the target area.

5. As to claim 15, Current density is the distribution of electric current per unit of area. Therefore, the "charge density" would necessarily be "approximately equal to the current multiplied by the pulse width of the stimulation pulse divided by the surface area of the electrode".

6. As to claim 16, According to Ohm's law, current is equal to voltage divided by resistance. Therefore, the current would necessarily be "approximately equal to the voltage level of the stimulation pulse divided by the impedance of the electrodes".

7. As to claims 18-19, Sieracki et al. discloses the device substantially as claimed but does not disclose the employment of drug infusion. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the therapy to include drug infusion in order to provide the predictable results of ensuring

that the patient does not endure chronic pain prior or after the threshold determining therapy.

8. As to claim 21, Sieracki et al. discloses the device substantially as claimed with the treatment of chronic pain but does not specifically disclose what disorder causes the chronic pain. It would have been obvious to one having ordinary skill in the art at the time the invention was made to treat chronic pain treatment of Sieracki et al. to provide relief of patients experiencing chronic pain as a result of dystonia or MS, in order to provide the predictable results of imparting relief to patient's experiencing chronic pain.

9. As to claim 45, Sieracki et al. discloses the device substantially as claimed but does not explicitly discloses determining if the polarity of the stimulation pulse is acceptable. It would have been obvious to one having ordinary skill in the art at the time the invention was made to monitor and assess whether the polarity of the stimulation pulse is acceptable in order to provide the predictable results of ensuring the patient is administered proper stimulation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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